DATA EVALUATION RECORD
ACUTE LC_{50} TEST WITH AN ESTUARINE/MARINE SHRIMP
OPPTS 850.1035

CHEMICAL: Neudorff's Insecticidal Soap Concentrate (A.I.: potassium salts of fatty acids)
PC Code No.: 128905

TEST MATERIAL: Potassium salts of fatty acids Purity: 46.8%

CITATION

Authors:	Fournier, A.E.
Title:	Neudorff's Insecticidal Soap Concentrate – Acute Toxicity to Mysid (*Americamysis bahia*), Under Flow Through Conditions, Following OPPTS Guideline 850.1035.
Study Completion Date:	April 22, 2011
Laboratory:	Smithers Viscient, Wareham, Massachusetts
Sponsor:	W. Neudorff GmbH KG, Great Falls Virginia
Laboratory Report ID:	13989.6114
MRID No.:	48469801
DP Barcode:	390987

Primary Reviewer: Stephen Carey, Biologist, OPP/EFED/ERB6

Signature: **Date:** May 2, 2012

Secondary Reviewer: Nathan Miller, Biologist, OPP/EFED/ERB6

Signature: **Date:** January 10, 2013

DISCLAIMER: This document provides guidance for EPA and PMRA reviewers on how to complete a data evaluation record after reviewing a scientific study concerning the acute toxicity of a pesticide to shrimp. It is not intended to prescribe conditions to any external party for conducting this study nor to establish absolute criteria regarding the assessment of whether the study is scientifically sound and whether the study satisfies any applicable data requirements. Reviewers are expected to review and to determine for each study, on a case-by-case basis, whether it is scientifically sound and provides sufficient information to satisfy applicable data requirements. Studies that fail to meet any of the conditions may be accepted, if appropriate; similarly, studies that meet all of the conditions may be rejected, if appropriate. In sum, the reviewer is to take into account the totality of factors related to the test methodology and results in determining the acceptability of the study.

1. STUDY PARAMETERS

Age or Size of Test Organism:	Juveniles (<24 hours)
Definitive Test Duration:	96 hours
Study Method:	Flow-through
Type of Concentrations:	Geometric mean-measured

2. CONCLUSIONS:

Results Synopsis
96-hr LC_{50}: >2.2 mg a.i./L 95% C.I.: n/a
NOAEC: 2.2 mg a.i./L
Probit Slope: N/A

Based on the results of this study, the active ingredient in **Neudorff's Insecticidal Soap Concentrate (potassium salts of fatty acids)** caused no acute effects to *Americamysis bahia* at the solubility limit.

3. ADEQUACY OF THE STUDY

A. Classification: Acceptable

B. Rationale: n/a

C. Repairability: n/a

4. BACKGROUND

5. GUIDELINE DEVIATIONS:

This study was conducted following procedures outlined in the U.S. Environmental Protection Agency Series 850 - Ecological Effects Test Guidelines, OPPTS Number 850.1035: *Mysid Acute Toxicity Test*. This study was conducted in compliance with all pertinent U.S. EPA Good Laboratory Practice Regulations (40 CFR, Part 160) with the following exceptions: routine dilution water and food contaminant screening analyses for pesticides, PCBs, and toxic metals were conducted at GeoLabs, Inc., Braintree, Massachusetts using standard EPA procedures. The following deviations from OCSPP 850.1035 were noted:

1. The physico-chemical properties of the test material were not reported.

This deviation was minor and does not impact the acceptability of the study.

6. SUBMISSION PURPOSE:

This study was submitted to provide data on the effects of Neudorff's Insecticidal Soap Concentrate (A.I.: potassium salts of fatty acids) on mortality and sub-lethal effects in the

saltwater mysid (*Americamysis bahia*) following acute exposure.

7. MATERIALS AND METHODS

A. Test Organisms

Guideline Criteria	Reported Information
Species Preferred species are *Americamysis bahia*, *Penaeus setiferus*, *P. duorarun*, *P. aztecus* and *Palaemonetes sp.*	Mysid shrimp, *Americamysis bahia*
Age Juvenile, mysids should be ≤24 hours old	Juveniles (<24 hours)
Supplier	In-house cultures
All shrimp are from same source?	Yes
All shrimp are from the same year class?	Yes

B. Source/Acclimation

Guideline Criteria	Reported Information
Acclimation Period minimum 10 days	Adult mysids were held in water from the same source and at the same temperature as the test for 14 days.
Wild caught organisms were quarantined for 7 days?	N/A
Were there signs of disease or injury?	No
If treated for disease, was there no sign of the disease remaining during the 48 hours prior to testing?	N/A
Feeding Mysids should be fed daily during testing.	Culture mysids were fed live brine shrimp nauplii, *Artemia sp.*, (source not reported). Juvenile mysids were fed daily during the test.

Guideline Criteria	Reported Information
Pretest Mortality <3% mortality 48 hours prior to testing	No mortality reported; however, adults showed no signs of stress or disease.

C. Test System

Guideline Criteria	Reported Information
Source of dilution water Soft reconstituted water or water from a natural source, **not** dechlorinated tap water	Dilution water was natural seawater collected at Cape Cod Canal, Bourne, Massachusetts that was filtered and diluted to a salinity of ~ 20 ± 3‰ with well water. Freshly-collected seawater was passed through a series of polypropylene core filters (20- and 5-micron) and pumped into a storage tank.
Does water support test animals without observable signs of stress?	Yes
Salinity 30-34 ‰ (parts per thousand) for marine (stenohaline) shrimp and 10-17 ‰ for estuarine (euryhaline) shrimp, weekly range < 6 ‰	19-20‰
Water Temperature Approx. 22 ± 1 °C	25 ± 2°C
pH 8.0-8.3 for marine (stenohaline) shrimp, 7.7-8.0 for estuarine (euryhaline) shrimp, monthly range < 0.8	7.6-7.9
Dissolved Oxygen Static: ≥ 60% during 1st 48 hrs and ≥ 40% during 2nd 48 hrs, Flow-through: ≥ 60%	>60% of saturation
Total Organic Carbon Should be <5 mg/L in reconstituted seawater	1.2 mg/L

Guideline Criteria	Reported Information
Test Aquaria 1. Material: Glass or stainless steel 2. Size: 19.6 L is acceptable for organisms 0.5 g (e.g. pink shrimp, white shrimp, and brown shrimp), 3.9 L is acceptable for smaller organisms (e.g. mysids and grass shrimp). 3. Fill volume: 15 L is acceptable for organisms 0.5 g, 2-3 L is acceptable for smaller organisms.	1. All-glass aquaria. 2. 30 x 15 x 20 cm. 3. 6.8 L.
Type of Dilution System Must provide reproducible supply of toxicant	Intermittent-flow proportional diluter
Flow Rate Consistent flow rate of 5-10 vol/24 hours, meter systems calibrated before study and checked twice daily during test period	9.9 vol/24 hours.
Photoperiod 16 hours light, 8 hours dark	16 h light, 8 h dark. Fluorescent bulbs at an intensity of 69 to 100 foot candles (740 to 1100 lux) at the solutions surface.
Solvents Not to exceed 0.5 ml/L for static tests or 0.1 ml/L for flow-through tests	None.

D. Test Design

Guideline Criteria	Reported Information
Range Finding Test If LC_{50} >100 mg/L with 30 shrimp, then no definitive test is required.	A range-finding study was conducted with a control and nominal test concentrations of 0.010, 0.10, 1.0, 10, and 100 mg a.i./L. Undissolved test substance was observed in the 10 and 100 mg/L treatment concentrations. After 96 hours, 10% mortality was observed among mysids <24 hours old in the 0.010 mg a.i./L treatment level, and 70% mortality for mysids of the 100 mg/L treatment. The definitive test concentrations were selected based on these results and consultation with the study sponsor.
Nominal Concentrations of Definitive Test Control & 5 treatment levels; a geometric series in which each concentration is at least 60% of the next higher one.	0 (negative control), 0.31, 0.63, 1.3, 2.5, and 5 mg a.i./L
Number of Test Organisms Minimum 20/level, may be divided among containers	20 mysids per group, equally divided among two replicates
Test organisms randomly or impartially assigned to test vessels?	Yes
Biological observations made every 24 hours?	Yes
Water Parameter Measurements 1. Temperature Measured constantly or, if water baths are used, every 6 hrs, may not vary > 1EC 2. DO and pH Measured at beginning of test and ever 48 h in the high, medium, and low doses and in the control	1. Temperature was measured in each test vessel daily. Additionally, temperature was measured continuously in Replicate B of the 0.31 mg a.i./L treatment. 2. DO and pH were measured in each test vessel of each treatment and control group daily.

Guideline Criteria	Reported Information
Chemical Analysis needed if solutions were aerated, if chemical was volatile, insoluble, or known to absorb, if precipitate formed, if containers were not stainless steel or glass, or if flow-through system was used	Samples were collected for analytical verification using HPLC with UV detection (205 nm).

8. REPORTED RESULTS

A. General Results

Guideline Criteria	Reported Information
Quality assurance and GLP compliance statements were included in the report?	Yes. Signed and dated No Data Confidentiality, GLP, and Quality Assurance statements were provided. This study was conducted in compliance with Good Laboratory Practice Standards as published by the U.S. Environmental Protection Agency (40 CFR Parts 160), with the following exception: routine dilution water and food contaminant screening analyses for pesticides, PCBs, and toxic metals were conducted at GeoLabs, Inc., Braintree, Massachusetts using standard EPA procedures.
Recovery of Chemical	<LOD to 44% of nominal concentration
Control Mortality Not more than 10% of control organisms may die or show abnormal behavior.	10% in the negative control
Raw data included?	Yes
Signs of toxicity (if any) were described?	Yes

Mortality

Concentration (mg a.i./L)		Number of Mysids	Cumulative Number Dead			
Nominal	Mean-measured		Hour of Study			
			24	48	72	96
Control	<0.034	20	1	2	2	2
0.31	0.081	20	1	3	3	3
0.63	<0.034	20	0	0	0	0
1.3	0.31	20	0	2	2	2
2.5	1.1	20	0	0	0	0
5.0	2.2	20	0	0	0	0

Other Significant Results:
All mysids in the control group and geometric mean-measured 1.1 and 2.2 mg a.i./L treatment groups appeared normal throughout the test, with no sublethal signs of toxicity observed. At test termination, 10, 15, and 10% mortality of mysids was observed in control and the 0.81 and 0.31 mg a.i./L geometric mean-measured treatment levels, respectively. The reviewer agrees that mortality in control and the 0.81 and 0.31 mg a.i./L treatment levels, respectively, is within naturally occurring variability and not likely an adverse response from exposure to the test material.

B. Statistical Results

Method: Visual interpretation since no concentration tested resulted in >50% mortality.

96-hr LC_{50}: >2.2 mg a.i./L 95% C.I.: n/a
NOAEC: 2.2 mg a.i./L
Probit Slope: N/A

9. VERIFICATION OF STATISTICAL RESULTS

Statistical Method: Visual interpretation

Parameter	Result
Binomial Test LC_{50} (95% C.I.)	n/a
Moving Average Angle LC_{50} (95% C.I.)	n/a
Probit LC_{50} (95% C.I.)	>2.2 mg a.i./L (visual interpretation)
Probit Slope	n/a
NOAEC	2.2 mg a.i./L (visual interpretation)

10. REVIEWER'S COMMENTS:

The reviewer's and the study author's results were in agreement; therefore, the author's results are presented in the Executive Summary and Conclusions sections of this DER.

The definitive test was conducted from February 22 to 26, 2011.

11. REFERENCES:

U.S. Environmental Protection Agency. 2012. Ecological Effects Test Guidelines. OCSPP 850.1035, Mysid Acute Toxicity Test.

U.S. Environmental Protection Agency. 2012. Ecological Effects Test Guidelines. OCSPP 850.1000, Special Considerations for Conducting Aquatic Laboratory Studies.